

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Yang et al.) ATTORNEY DOCKET: 0109015-024
SERIAL NO.: 10/047,352) GROUP ART UNIT: 1649
FILED: January 14, 2002)
TITLE: Stable Neural Stem Cell Line Methods
DATE: March 13, 2009

MAIL STOP ISSUE FEE
Commissioner for Patents
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Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 35 U.S.C. 154(b) and 37 C.F.R. §§ 1.702 - 1.705

This application for Patent Term Adjustment is being filed pursuant to 25 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702-1.705 and requests that an additional 490 days of patent term adjustment be granted in addition to the 200 days provided in the Notice of Allowance mailed on September 10, 2007. Please deduct the fee set forth in 37 C.F.R. 1.18(e), or any additional fee due, from deposit account number 02-1818. Enclosed herewith is a statement of facts supporting this application for Patent Term Adjustment as required by 37 C.F.R. § 1.705(b)(2).

STATEMENT OF FACTS UNDER 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.705(b)(2) Applicants respectfully submit the following Statement of Facts in support of their Application for Patent Term Adjustment. Applicants hereby request that an additional 490 days of adjustment be granted in addition to the 200 days of patent term adjustment previously accorded in the Notice of Allowance mailed on January 13, 2009. The requested 490 additional days are the number of days between January 15, 2005 (the day after three years from the application's filing date) and May 19, 2006 (the filing of the first RCE). Applicants are entitled to this additional patent term adjustment under 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. §§ 1.702(b) and 1.703(b)(1) in view of *Wyeth et al., v. Dudas*, Civ. Action No. 07-1492 (JR) (D.D.C. September 30, 2008).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are relevant here. The first is found in subsection (b)(1)(A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: 14 months for a first office action; four months to respond to a reply; four months to issue a patent after the issue fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are referred to as “A delays.” The second relevant provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the “B delay.” According to *Wyeth*, if an “A delay” occurs on one calendar day and a “B delay occurs on another, they do not overlap and § 154(b)(2)(A) does not limit the extension to one day. *Id.* at 8.

The B delay regulations appear at 37 C.F.R. § 1.702(b) and state that the term of a patent shall be adjusted if its issuance was delayed due to the failure of the USPTO to issue the patent within three years after filing of the application. Under § 1.703(b)(1), the amount of patent term adjustment based upon the USPTO’s failure to issue a patent within three years excludes the amount of time between filing of an RCE and the issue date of the patent. Since the period between the filing of an RCE and the issue date is excluded under § 1.703(b)(1), the amount of adjustment pursuant to § 1.702(b) can be determined independent of the issue date for the present application as an RCE was filed on May 19, 2006. Thus, Applicants are entitled to an additional patent term adjustment under §§ 1.702(b) and 1.703(b)(1) equal to the number of days between (i) the day after three years from the filing of the application; and (ii) the filing of an RCE. These B delay days do not fall on the same calendar day as any A delay days. The present application was filed on January 14, 2002; the day after three years from the filing date is therefore January 15, 2005. Additionally, an RCE was filed in the present application on May 19, 2006. Thus, pursuant to § 1.703(b)(1), Applicants are entitled to a patent term adjustment of a period of equal to the number of days between January 15, 2005 and May 19, 2006. This period of time is equal to 490 days and was not included in the 200 days of patent term adjustment stated in the Notice of Allowance. Applicants respectfully request that the patent

granted on the present application be granted an additional 490 days of patent term adjustment pursuant to §§ 1.702(b) and 1.703(b)(1) in addition to the 200 days of patent term adjustment indicated in the Notice of Allowance. Thus, pursuant to § 1.703(f), the present application is entitled to a total of 690 days of patent term adjustment.

A summary of the relevant dates is as follows:

Application filing Date:	January 14, 2002
Application filing Date + 14 months:	March 14, 2005
Date of first Office Action:	October 6, 2004
Filing Date + 3 years:	January 14, 2005
RCE filing Date:	May 19, 2006
Patent Issue Date:	TBD

Adjustment Period	Number of Days	37 C.F.R.
March 15, 2003 – October 6, 2004	572	§§ 107.02(a)(1) and 1.703(a)(1)
April 28, 2005	-1	§ 1.704(b)
April 28, 2005 – October 20, 2005	-176	§ 1.704(b)
April 10, 2006 – May 19, 2006	- 39	§ 1.704(b)
October 18, 2006 – January 17, 2007	-92	§ 1.704(b)
January 18, 2007	-1	§ 1.704(b)
July 20, 2007 – August 21, 2007	-30	§ 1.704(b)
December 14, 2007 – October 14, 2008	- 215	§ 1.704(b)
January 15, 2005 – May 19, 2006	489	§ 1.702(b) and 1.703(b)
Total	689	

Pursuant to § 1.705(b)(2)(iii), Applicants submit that the present application is not subject to a terminal disclaimer.

Pursuant to § 1.705(b)(2)(iv)(B), Applicants submit that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the present application as set forth in § 1.704.

In the event that the Office views this Application for Patent Term Adjustment under § 1.705(b) as a premature request for reconsideration of patent term adjustment under § 1.705(d), Applicant hereby reserves the right to resubmit the foregoing arguments after grant of the patent and any other arguments in support of patent term adjustment. Additionally, Applicants do not waive any other bases for patent term adjustment to which they may be entitled under § 1.705(d).

Conclusion

Applicants submit that in view of the foregoing, the present application is entitled to an additional 490 days of patent term adjustment beyond the 200 days to which the Office has already determined the present application is entitled. Applicants therefore request the USPTO to reinstate the period of term adjustment accordingly. If, for any reason, direct communication would help facilitate this request for reconsideration, please feel free to contact the undersigned.

Respectfully submitted,



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